In re Patent Application of
John Alfred Wilkinson
Serial No. 10/019,353
Filed April 25, 2002

REMARKS

Applicant herein responds to the outstanding Office action and requests that the Examiner take notice of new counsel, as per the undersigned.

The Claims Are Definite

The Examiner's concerns regarding the clarity of the claim language have been addressed through the amendment of independent claim 1 to eliminate the expression "based on" and substitute the term "containing." The expression "based on" is not included in any other pending claim. Accordingly, Applicant respectfully requests that the Examiner withdraw the claim rejections under Section 112.

The Claims Are Nonobvious Over The Cited Art

The pending claims have been rejected by the Examiner as obvious and unpatentable under Section 103(a) over Eini (EP Publication No. 0 495 684 A1), in view of Coats (US 4,178,372), Himmelstein et al. (WO 95/35093), or Precopio (US 5,858,383).

Claims 1 and 75 are the only pending independent claims, consequently Applicant will focus these remarks on these two claims which, if found patentable, their respective dependent claims will also be patentable, as they add yet additional distinguishing features to the claimed invention.

The Examiner has acknowledged that Eini, the primary reference, does not mention a gel based on polymethacrylate, nor on *Aloe vera*. Applicant has additionally searched an electronic copy of the Eini reference and finds no mention of or teaching related to polypropylene glycol. Accordingly, those skilled in the art would find no teaching in the Eini reference that would guide them to achieving the invention recited in independent claim

1, which includes a synthetic gelling agent containing glyceryl polymethacrylate and propylene glycol. The skilled would also find no teaching in the Eini reference that would lead them to arrive at the invention of independent claim 75, which recites a composition comprising at least one anti-pruritic agent containing an extract of *Aloe vera*. Absent those teachings in the Eini reference, the obviousness rejections must rely on the additional references cited by the Examiner.

The Examiner cites the Coats reference (US 4,178,372) as teaching a hypoallergenic gel made from *Aloe vera*. Applicant points out, however, that Coats does not disclose, or even suggest, a synthetic gelling agent as recited in claim 1. Nor does Coats describe an anti-pruritic agent. Accordingly, there is no teaching in the Coats reference which would be combinable with Eini to lead the skilled to the invention recited in claim 1, which requires a synthetic gelling agent, nor to the invention recited in claim 75 which requires at least one anti-pruritic agent containing an extract of *Aloe vera*.

The Himmelstein et al. reference (WO 95/35093 and its US counterpart Patent No. 5,599,534) is cited by the Examiner for teaching adjustable gel formation for controlling release of an active agent. Applicant respectfully points out that Himmelstein et al. describe a gel composition which exhibits reversible gelling under the influence of changing pH. Himmelstein et al. provide the following description of their invention (see column 4, lines 10-18 of US 5,599,534:

> An example of a reversibly-gelling composition of the invention which exhibits an increase in viscosity in response to variation in pH over a pre-determined range comprises an aqueous solution that includes a stable combination of at least one pharmaceutically acceptable pH-responsive gelling polymer

and at least one other pharmaceutically acceptable, thermally nonresponsive polymer in amounts sufficient to produce the reversible change in pH over the pre-determined pH range.

Preferred pH-responsive gelling polymers are described in said Himmelstein et al. reference at column 6, lines 43-54 and 60-62. The reference, however, makes no mention of propylene glycol, which is a component of the present gelling agent as recited in claim 1. Neither does the reference describe an anti-pruritic agent including an extract of *Aloe vera*, which is a component of the composition recited in claim 75. Accordingly, the reference by Himmelstein et al., even when combined with the Eini reference, provides no teaching that would lead the skilled to the inventions recited in independent claims 1 and 75.

The Precopio reference (US 5,858,383) describes a water-soluble or water-dispersible, substantially air-impermeable liquid composition and a method for the topical treatment of ectoparasites on animal skin utilizing the composition. The Precopio reference does not describe a composition comprising essential oils, does not describe a gelling agent including propylene glycol, and does not describe an anti-pruritic agent.

Applicant respectfully emphasizes that Precopio teaches a composition which acts by suffocating ectoparasites by denying air when they are covered by the composition, for example, as on the skin or hair. The Precopio composition denies the ectoparasite the oxygen needed to breathe, consequently, suffocating them. For this reason, the Precopio invention does not work well against ectoparasite eggs, which must be physically removed, rather than killed, by the action of the composition. In support of these assertions, please see the following quotes from the Precopio reference.

By substantially air-impermeable is meant that the composition does not contain sufficient air nor does it permit air to penetrate the composition in a quantity that would prevent the composition from suffocating the ectoparasites. (Column 2, lines 7-12).

The above treatment will kill all motile stages of lice, but the nits (eggs) are not easily destroyed, and hence repeat treatments will probably be necessary.

However, a composition of the invention can be used in the above method which will also effectively remove the nits as well as killing the ectoparasites. Component I) of the composition is the same water-soluble or water-dispersible, substantially air-impermeable liquid used in the above-described method of the invention. Component II) is one or more substances that remove nits, usually by loosening the adhesive bond that fastens the nits to the skin or hair. Such substances include formic acid, and enzymes that loosen the nits by differential hydration. Such enzymes include one or more of oxidoreductase, transferase, lyase, hydrolase, isomerase, and ligase. Concentrations of Component II) substances that are effective for removing nits depend on the particular substance chosen, but generally range from 0.0001 to 10% by weight of the composition. However, since formic acid can be caustic to the skin, when formic acid is used, the

quantity of formic acid in the composition should be as small as possible, consistent with nit-removing effectiveness. (Column 5, lines 28-49).

The Precopio reference therefore teaches completely away from the presently claimed invention, which relies on the toxic effect of essential oils on the ectoparasites. For that reason, Precopio is not combinable with the Eini reference, which is the only cited reference which describes essential oils. If combined with Eini, the Precopio formulation would have be modified to the extent that it would lose its ability to function as intended by its inventor. Accordingly, it would be improper to combine the Precopio reference in an obviousness rejection because the combination would completely change the mode of action of the reference, destroying its original teaching.

The Office Has Not Established A Prima Facie Case For Obviousness

The Federal Circuit has long established that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1987).

It is established that a court will first look to the prior art references to determine whether "the references by themselves . . . suggest doing what [Applicants] have done." In re Clinton 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976); MPEP § 2143.01. The Office Action has not established such showing.

Even if all the elements of a claim were to be disclosed in the various prior art references, which Applicant disputes in this case, the claimed invention as a whole cannot be said to be obvious without some reason given in the prior art why a skilled worker would

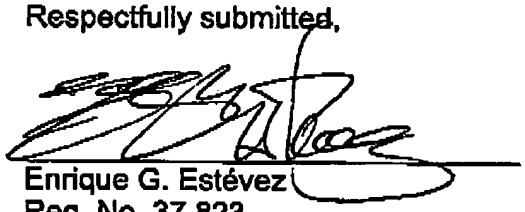
combine the teachings of the references to arrive at the claimed invention. In re Regel, 188 USPQ 132 (CCPA 1975). The Office Action does not point out any such reason given in the prior art. In the absence of such reason or suggestion, the Office Action fails to establish a *prima facie* case of obviousness.

Conclusion

In view of the amendments and the remarks presented herein, it is submitted that claims 1 and 75 are patentable. In addition, their respective dependent claims, which recite yet further distinguishing features, are also patentable and require no further discussion.

If the further prosecution can be facilitated through a telephone conference between the Examiner and the undersigned, the Examiner is respectfully requested to telephone the undersigned.

Respectfully submitted,



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